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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Lifestyle Investments, LLC, individually and on behalf of all others similarly situated, Plaintiff, v. Amicus Therapeutics, Inc., and John F. Crowley, Defendants.	Case No. _____ **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **Jury Trial Demanded**

Plaintiff Lifestyle Investments, LLC ("Plaintiff") residing at 60 E. Simpson Avenue, Jackson, Wyoming, by and through its attorneys, alleges upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters, based upon the investigation conducted by and through his attorneys, which included, among other things, a review of documents filed by Defendants (defined below) with the Untied States Securities and Exchange Commission (the

"SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Defendant Amicus Therapeutics, Inc. ("Amicus" or the "Company") common stock between September 15, 2015 through October 1, 2015, inclusive (the "Class Period"). This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

2. On the same day that Amicus met with the United States Food and Drug Administration ("FDA") to discuss the development of its new drug, migalastat, Amicus and its Chief Executive Officer, John F. Crowley ("Crowley", and together with Amicus, the "Defendants"), issued a false and misleading press release describing that meeting and its outcome to Amicus investors.

3. Immediately after the meeting with the FDA had concluded, Amicus touted to the market in a September 15, 2015 press release that it had engaged in a "collaborative" meeting with the FDA, which represented a "significant milestone" and was a "great example of FDA and industry working together to advance innovative therapies for people living with debilitating genetic disorders."

4. Crowley and Amicus told the market through the September 15 press release that the FDA's guidance during the meeting "further reinforce[d] our confidence in [Amicus' new drug application] package and post-marketing confirmatory study we are preparing for submission by the end of this year."

5. The FDA advises companies that meet with the agency to carefully summarize their understanding of the meeting's outcome back to the FDA staff at the conclusion of the meeting. This ensures that the FDA and the company have a mutual understanding of the meeting's outcome and follow-up actions.

6. Yet the statements made in Amicus' September 15 press release were false and misleading. In fact, at the September 15 meeting, the FDA expressed concerns about Amicus' forthcoming new drug application ("NDA") for migalastat. Following Amicus' receipt of the final minutes from the September 15 meeting and further discussions with the agency, the Company was forced to acknowledge that its September 15 press release was false. Indeed, Amicus corrected the misstatements in its September 15 release just two weeks later, on October 2, 2015, by declaring that it was no longer on track to submit the NDA in 2015.

7. As soon as this news was revealed to the stock market, Amicus stock plummeted more than 50%, dropping from its closing price of $13.75 on October

1, 2015 to open at $5.98 and close at $6.39 on October 2, 2015, on tremendously high volume.

JURISDICTION AND VENUE

8. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and § 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, as well as under the common law.

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and § 27 of the Exchange Act, 15 U.S.C. § 78aa.

10. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

11. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b), as Amicus has its principal executive offices located in this District and conducts substantial business therein.

12. In connection with the acts, omissions, conduct and other wrongs in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce including but not limited to the United

States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

13. Plaintiff Lifestyle Investments, LLC is a limited liability company organized under the laws of Wyoming, with its principal place of business in Jackson, Wyoming. Plaintiff acquired and held shares of the Company at artificially inflated prices during the class period and has been damaged by the revelation of Amicus' material misrepresentations and material omissions.

14. Defendant Amicus Therapeutics, Inc., is a Delaware Corporation with its principal place of business in Cranbury, New Jersey. Amicus trades on the NASDAQ stock exchange under the ticker symbol "FOLD," and claims that it is a "biotechnology company at the forefront of therapies for rare and orphan diseases," that "has a robust pipeline of advanced therapies for a broad range of human genetic diseases."

15. Defendant John F. Crowley is the Chairman and Chief Executive Officer of Amicus.

16. Crowley, because of his position as Chairman and Chief Executive Officer of Amicus, possessed the power and authority to control the content and form of Amicus' annual reports, quarterly reports, press releases and presentations to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*,

the market. Crowley authorized the publication of the press release alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent its issuance or to cause it to be corrected. Because of his position with the Company and his access to material non-public information available to him but not to the public, Crowley knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were false and misleading. Crowley is liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

17. Amicus Therapeutics, Inc. is a biotechnology company that developed therapies for rare and orphan diseases.

18. The Company has developed a therapy, an oral small molecule pharmacological chaperone called migalastat, for the treatment of Fabry disease. Amicus' treatment purports to be a new option for patients afflicted by Fabry disease who have amenable mutations.

19. A new drug application, or "NDA" is the vehicle in the United States through which drug sponsors formally propose to the United States Food and Drug Administration ("FDA") new pharmaceuticals for sale and marketing. Among other things, the FDA uses this new drug application process to make determinations about the safety and efficacy of the proposed new drugs.

20. Prior to submitting an NDA, pharmaceutical companies can engage in a process with the FDA, which can include a "Pre-NDA" meeting to discuss the development of the drugs at issue.

21. Executives from Amicus attended such a meeting with the FDA on September 15, 2015, where it discussed its development of migalastat.

22. Immediately following the meeting, on September 15, 2015, Amicus issued an upbeat press release, touting the outcome of the Company's meeting with the FDA and stating that the company planned to submit a New Drug Application for migalastat in the fourth quarter of 2015:

> **Amicus Therapeutics Plans to Submit New Drug Application (NDA) for Migalastat for Fabry Disease Following Positive Pre-NDA Meeting With FDA**
>
> NDA Submission to Request Accelerated Approval (Subpart H) on Track for 4Q15
>
> CRANBURY, N.J., Sept. 15, 2015 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq:FOLD), a biotechnology company at the forefront of therapies for rare and orphan diseases, today announced that a Pre-NDA meeting was held with the U.S. Food and Drug Administration (FDA) to discuss the oral small molecule pharmacological chaperone migalastat for the treatment of Fabry disease. The unique mechanism of action of migalastat represents a new personalized medicine option for Fabry patients who have amenable mutations.
>
> Based on FDA feedback at the Pre-NDA meeting, reduction in disease substrate (kidney interstitial capillary GL-3) will serve as the primary endpoint, supported by the totality of data from completed clinical studies. Amicus remains on track to submit an NDA in the fourth quarter of 2015 under Accelerated Approval, which is only available to therapies for severe and life-threatening conditions that address

> significant unmet medical needs. Discussions with the FDA on the Phase 4 program required for a Subpart H approval have focused on a study of the effect of migalastat on gastrointestinal symptoms associated with Fabry disease. In addition to the NDA submission, Amicus intends to submit for review the protocol for the Phase 4 study confirming the positive effects of migalastat on gastrointestinal symptoms in these patients.
>
> "Our collaborative Pre-NDA meeting represents a significant milestone for the Fabry community in the United States and is a great example of FDA and industry working together to advance innovative therapies for people living with debilitating genetic disorders," stated John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics. "The guidance provided by FDA during the Pre-NDA meeting further reinforces our confidence in the NDA package and post-marketing confirmatory study we are preparing for submission by the end of this year. In addition, our marketing submission for migalastat in Europe is already being reviewed under Accelerated Assessment and an Opinion is expected by year-end. With defined regulatory pathways for migalastat in both the U.S. and EU, we are rapidly executing our global strategy to bring this novel personalized medicine to as many people living with Fabry disease as quickly as possible."

23. Those that follow Amicus reacted positively to the press release. One Twitter user, @bradloncar, stated on September 15 "$FOLD – 4Q15 AA NDA still on track after pre-NDA meeting. With reduction in disease substrate as primary endpoint," while linking to the press release. Another Twitter user, @XsleepftLearner, tweeted "[positive] NDA news," along with a link to the press release.

24. The website Fierce Biotech also reported on the news in an article authored by Damian Grade on September 15, 2015, concluding that Amicus "has

reached an accord with US Regulators and is on track to submit its rare disease treatment for FDA approval before the end of the year." Other financial news websites also picked up on the news.

25. While Crowley stated that "[t]he guidance provided by the FDA during the [September 15, 2015] Pre-NDA meeting further reinforces our confidence in the NDA package and post-marketing confirmatory study we are preparing for submission by the end of this year," the FDA apparently provided no such guidance to Crowley or others at Amicus during the September 15, 2015 meeting.

26. Indeed, just two weeks later, on October 2, 2015, the company abruptly issued a press release contradicting Amicus' stated account of the September 15, 2015 meeting. While the headline innocuously indicated that Amicus was providing a "U.S. Regulatory Update," the press release actually informed the stock market that Amicus' September 15, 2015 press release incorrectly represented the company's meeting with the FDA:

> **Amicus Therapeutics Provides U.S. Regulatory Update for Migalastat Monotherapy**
>
> CRANBURY, N.J., Oct. 2, 2015 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq:FOLD), a biotechnology company at the forefront of therapies for rare and orphan diseases, today announced additional regulatory guidance from the U.S. Food and Drug Administration (FDA) on the oral small molecule pharmacological chaperone migalastat for the treatment of Fabry disease.

> Amicus has received final FDA minutes from the September pre-NDA meeting and has conducted additional follow-up interactions with the Agency this week. In conjunction with the Agency, Amicus is further evaluating several U.S. pathways including potentially generating additional data on migalastat's effect on gastrointestinal symptoms in Fabry disease to support submission requesting full approval as well as a Subpart H strategy. In addition, the Agency has requested further integration of existing clinical data across studies which will require more time to complete. Based on this guidance from the FDA, Amicus does not anticipate being in a position to submit the NDA for migalastat monotherapy in the United States by the end of this year. The timing of an NDA submission will be based on the determination of the optimal regulatory pathway.
>
> "Amicus remains committed to making migalastat available to Fabry patients with amenable mutations in the U.S. as rapidly as possible. We are appreciative of the FDA's ongoing collaboration in this program," stated John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics.

Amicus' Stock Plummets Over 50%
After The Misstatements Are Revealed

27. After this so-called "Regulatory Update" revealed to the market that Amicus had misstated the nature and outcome of the September 15, 2015 Pre-NDA meeting, Amicus stock plummeted.

28. Amicus' stock price, which closed at $13.75 per share on October 1, 2015, and traded as high as $18.23 during the period between September 15, 2015 and October 1, 2015, opened on October 2, 2015 at $5.98 per share and traded as low as $5.69 per share, before closing at $6.39 per share.

29. Amicus' October 2, 2015 press release, which revealed the false and misleading nature of the company's and Crowley's September 15, 2015

statements, represented a one-day loss to investors of at least $7.36 per share—more than 50%—and slashed over $750 million from the Company's market capitalization, costing investors tens of millions of dollars.

30. Joseph P. Schwartz, an analyst for investment bank Lerink Partners, LLC, who covers Amicus, is reported to have stated that the company's October 2, 2015 press release came as a "huge surprise" to investors and noted that "[a]dditional clinical data will be required to bolster the case for approval in the US."

FDA Guidance Encourages Companies To Leave The FDA Meeting With A Complete Understanding Of Its Outcome

31. The FDA has issued a publication entitled *Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants.*

32. Among other things, the FDA advises:

> Before the end of the meeting, FDA attendees and the requested attendees should summarize the important discussion points, agreements, clarifications, and action items. Generally, the requester will be asked to present the summary to ensure that there is mutual understanding of meeting outcomes and actions. FDA staff can add or further clarify any important points not covered in the summary and those items can be added to the meeting minutes.

33. Had Amicus followed this guidance, it would have known that "[t]he guidance provided by FDA during the Pre-NDA meeting" did not "further reinforce [Amicus'] confidence in the NDA package and post-marketing

confirmatory study we are preparing for submission by the end of this year," as Crowley stated in the September 15, 2015 press release.

34. As a columnist for TheStreet.com Adam Feuerstein put it: "[i]n the rush to deliver stock performance and good news to investors, drug company CEOs are getting too aggressive with regulatory forecasts. They walk out of FDA meetings believing what they want to hear—and blab happily to investors—instead of waiting for definitive decisions." Feuerstein further advised that "Biotech CEOs should shut their mouths about regulatory plans until they receive definitive word from the FDA."

35. Crowley and Amicus either (a) acted recklessly by failing to fully disclose all of the details of Amicus' September 15 Pre-NDA meeting with the FDA, or by failing to fully disclose that it did not follow FDA guidance to "ensure that there is mutual understanding of meeting outcomes and actions" prior to issuing its September 15 press release, or (b) worse, Crowley and Amicus followed FDA guidance, and thus knew or should have known that the FDA had concerns that would not allow Amicus to file an NDA in the fourth quarter of 2015, and knowingly made false statements in the September 15, 2015 press release.

Amicus Insiders Sold Shares During The Class Period

36. Shockingly, numerous Amicus insiders—including those likely to have attended the September 15, 2015 FDA meeting, including the Company's

Chief Scientific Officer, President and Chief Operating Officer—sold shares after the false and misleading September 15, 2015 press release was issued, and before the October 2, 2015 "Regulatory Update" disclosed its falsity. These insiders knew or should have known that the September 15, 2015 press release contained a false description of the FDA meeting.

37. Hung Do, Ph.D., Amicus' Chief Scientific Officer, sold 25,000 shares on September 15, 2015 at an average price of $17.7467 per share, grossing approximately $443,667.

38. Bradley Campbell, Amicus' President and Chief Operating Officer, sold 13,001 shares on September 21, 2015 at an average price of $16.7838 per share, grossing approximately $218,206.

39. William D. "Chip" Baird, Amicus' Chief Financial Officer, sold 15,236 shares on September 21, 2015 at an average price of $16.7783 per share, grossing approximately $255,634.

40. Kenneth W. Peist, Esq., Amicus' Vice President, Legal and Intellectual Property, sold 10,000 shares on October 1, 2015 at an average price of $13.1362 per share, grossing approximately $131,362.

41. Daphne Quimi, CPA, Amicus' Vice President, Finance and Corporate Controller, sold 11,250 shares on October 1, 2015 at an average price of $13.1343 per share, grossing approximately $147,760.

42. Furthermore, Amicus closed an acquisition of Scioderm, Inc., a privately held company, on September 30, 2015. That acquisition was originally announced on August 30, 2015. Defendant Crowley, in addition to serving as Amicus' Chief Executive Officer and Chairman, is also on the Board of Directors of Scioderm, Inc. Typically, compensation paid to directors of privately held corporations includes a stock-based component, thus giving Crowley an interest in the consideration paid by Amicus as part of its Scioderm acquisition.

43. When the Scioderm, Inc. acquisition was announced in August, the terms of the acquisition called for Amicus to pay $125 million in cash and $104 million in stock to Scioderm, Inc. shareholders, a total of $229 million in consideration.

44. When the transaction closed on September 30, 2015, the terms of the transaction had changed. Scioderm, Inc. investors were paid more *cash* than originally announced in August: $141 million in cash and $88 million in stock. This represented the same $229 million in total consideration, but included less Amicus stock than originally planned. This is true despite the fact that the original merger agreement established a fixed per-share value of the Amicus stock included in the deal.

45. Amicus has not explained why Scioderm, Inc. investors received *less* stock in the transaction. Of course, just days after the transaction closed, Amicus stock plummeted.

CLASS ACTION ALLEGATIONS

46. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Class of all persons and entities who purchased or otherwise acquired Amicus common stock between September 15, 2015 and October 1, 2015, inclusive. Excluded from the Class are Defendants, directors, and officers of Amicus, as well as their families and affiliates.

47. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

48. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether the Exchange Act was violated by Defendants;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the price of Amicus stock was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damages.

49. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

50. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

51. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

FRAUD ON THE MARKET

52. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiff and other members of the Class purchased Amicus common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

53. At all relevant times, the markets for Amicus common stock were efficient for the following reasons, among others: (i) Amicus filed periodic public reports with the SEC; and (ii) Amicus regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire serves and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the

Class relied on the price of Amicus common stock, which reflected all information in the market, including the misstatements by Defendants.

NO SAFE HARBOR

54. The statutory safe harbor provided for forward-looking statements under certain statements does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

55. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

LOSS CAUSATION

56. On October 2, 2015, before the markets opened, Amicus disclosed that it "does not anticipate being in a position to submit the NDA for migalastat monotherapy in the United States by the end of this year," contrary to its public statements on September 15, 2015. At the time the market opened on October 2, 2015, Amicus stock declined by $7.77 per share, or 56.5%. This decline is directly attributable to the October 2, 2015 corrective press release.

CAUSES OF ACTION

COUNT I
Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder
(Against All Defendants)

57. Plaintiff repeats and realleges each and every allegation contained above as it fully set forth herein.

58. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

59. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon those who purchased or otherwise acquired Amicus securities during the Class Period.

60. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Amicus common stock. Plaintiff and the Class would not have purchased Amicus stock at

the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

COUNT II
Violation of § 20(a) of the Exchange Act
(Against John F. Crowley)

61. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

62. Crowley acted as a controlling person of Amicus within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of his high-level position at the Company, Crowley had the power and authority to cause or prevent Amicus from engaging in the wrongful conduct complained of herein. Crowley was provided with or had unlimited access to the September 15, 2015 press release and other statements alleged by Plaintiffs to be misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of these materials or to cause them to be corrected so as not to be misleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

63. Determining that this action is a proper class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to

Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

64. Awarding compensatory and punitive damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount proven at trial, including pre-judgment and post-judgment interest thereon.

65. Awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

66. Awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

67. Plaintiff demands a trial by jury.

DATED: October 7, 2015

GARDY & NOTIS, LLP

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